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10/668,601	09/24/2003	Aviv Shaish	25727	1529

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EXAMINER	
FLOOD, MICHELE C	
ART UNIT	**PAPER NUMBER**
1655	

DATE MAILED: 08/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/668,601	SHAISH ET AL.	
	Examiner	Art Unit	
	Michele Flood	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 May 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/20/05*.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *4/6/2005*.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

9.00

DETAILED ACTION

Acknowledgment is made of the receipt and entry of the amendment filed on May 9, 2005. Further acknowledgment is made of newly submitted Claims 19-26 and the declaration of Aviv Shaish filed under Rule 132.

The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office action.

Claims 1-26 are under examination.

Response to Arguments

Claim Rejections - 35 USC § 112

Claims 1, 3-10 and 19-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Newly applied as necessitated by amendment.

Claims 1 and 19, recite "the disease", in line 1. There is insufficient antecedent basis for these limitations in the claims.

All other cited claims depend directly or indirectly from rejected claims and are, therefore, also, rejected under U.S.C. 112, second paragraph for the reasons set forth above.

Claim Rejections - 35 USC § 102

Claim 1 as amended and Claims 8-10 remain rejected under 35 U.S.C. 102(b) as being anticipated by Levy et al. (U). Applicant's argument and the declaration of Aviv Shaish have been thoroughly considered. However, the rejection remains for the reasons set forth in the previous Office action and for the reasons set forth below.

Applicant claims a method for treating a disease selected from diabetes mellitus and atherosclerosis comprising administrating to a subject an effective amount of crude *Dunaliella* powder, thereby treating the disease. Applicant further claims the method according to Claim 1, wherein said crude *Dunaliella* powder is administered orally; wherein said algae is *Dunaliella bardawil*; and, wherein said powder is encapsulated.

Applicant's arguments are directed to limitations not commensurate in scope to the instantly claimed subject matter, namely the treatment of atherosclerosis. Thus, the rejection remains the same because Levy teaches a method of treating patients suffering from diabetes mellitus and at high risk of developing atherosclerosis comprising administering an effective amount of a crude extract obtained from *Dunaliella bardawil* in encapsulated form. Levy teaches that the administration of the algal extract inhibited the oxidation of LDL derived from diabetic patients.

The reference anticipates the claimed subject matter.

Claims 2, 16 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Itoh et al. (V* and W, Translation of foreign non-patent literature provided herein.). Newly applied as necessitated by amendment.

Applicant claims a method for increasing HDL cholesterol levels in the plasma of a subject in need thereof comprising administering an effective amount of *Dunaliella bardawil* powder, thereby increasing the HDL cholesterol level.

Itoh teaches a method for increasing HDL cholesterol levels in the plasma of a subject in need thereof comprising orally administering an effective amount of *Dunaliella bardawil* powder, thereby increasing the HDL cholesterol level.

The reference anticipates the claimed subject matter.

Claim Rejections - 35 USC § 103

Claim 1 as amended and Claims 3-10 is/remain rejected under 35 U.S.C. 103(a) as being unpatentable over Levy et al. (U) in view of Beck (A*), Pan et al. (B*), Heyman et al. (C*) and Smith (N).

Applicant's arguments and the declaration of Aviv Shaish have been fully considered but they are not deemed persuasive because the cited references provide the suggestions and motivation to the claimed invention.

In response to applicant's argument that the examiner has combined an excessive number of references, reliance on a large number of references in a rejection does not, without more, weigh against the obviousness of the claimed invention. See *In re Gorman*, 933 F.2d 982, 18 USPQ2d 1885 (Fed. Cir. 1991). In the instant case, the teachings of Levy were relied upon for the reasons set forth in the previous Office action and for the reasons set herein. Because Levy taught the instantly claimed method for treating diabetes mellitus except for the instantly claimed ingredients, the references of

Beck, Pan, Heyman and Smith were relied upon because the cited references taught that fibrates, thiazolidinediones or a combination thereof were known in the art for their beneficial functional effect to treat diabetes mellitus. For instance, Beck taught a method for the treatment of normolipidaemic diabetes mellitus comprising orally administering an effective amount of bezafibrate. Secondly, Pan taught a method of reducing the risk of or treating diabetes mellitus comprising administering an effective amount of an antihyperlipoproteinemic agent, *e.g.*, fenofibrate, gemfibrozil, clofibrate, bezafibrate, ciprofibrate and clinofibrate in combination with a cholesterol lowering drug, ACE inhibitor, in Column 9, lines 32-58. For example, in Column 15, line 58 to Column 16, line 2, Pan teaches administering gemfibrozil capsules either alone in combination with a cholesterol lowering drug, ACE inhibitor in the treatment of diabetes mellitus. Thirdly, Heyman taught a method of treating diabetes mellitus comprising administering an effective amount of a thiazolidinedione, *e.g.,* troglitazone, BRL 49653 , pioglitazone, ciglitazone, WAY-120,744, englitazone, AD 5075, and darglitazone, in combination with an RXR agonist to a subject. Fourthly, Smith taught a method of treating diabetes mellitus comprising administering rosiglitazone.

Thus with Levy providing the motivation to orally administer an effective amount of crude *Dunaliella* powder to diabetic patients at risk of developing atherosclerosis, and with Beck teaching that the oral administration of bezafibrate reduces the insulin level in normolipidaemic patients suffering from diabetes mellitus; and, with Pan teaching that his method reduces or prevents the onset of diabetes mellitus and the onset of atherosclerosis in mammals, in Column 4, lines 27-34; and, with Heyman teaching that

the combination of an RXR agonist and a PPARγ agonist, *i.e.,* a thiazolidinedione, achieves synergistic action of the RXR/ PPARγ heterodimers so as to enhance adipogenic and antidiabetic effects of PPARγ, in Column, 2, lines 5-11; and, with Smith teaching that his method for treating diabetes mellitus comprising administering rosiglitazone provides a beneficial effect on glycaemic control, on page 1, lines 19-22, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the instantly claimed old and well-known ingredients to provide a method for treating diabetes, as suggested by the cited references. As each of the references clearly indicate that the various proportions and amounts of the ingredients used in the claimed composition or the claimed composition/pharmaceutical combinations are result variables, they would have been routinely optimized by one of ordinary skill in the art in practicing the invention disclosed by that reference. Therefore, the invention as a whole was clearly *prima facie* obvious in the absence to the contrary.

Newly submitted Claims 19-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levy et al. (U) in view of Pan et al. (B*), Craig et al. (O) and Druzgala et al. (D*), and further in view of Boulous et al. (E). Newly applied as necessitated by amendment.

Applicant's arguments and the declaration of Aviv Shaish have been fully considered but they are not deemed persuasive because the cited references provide the suggestions and motivation to the claimed invention for all of the reasons clearly set forth herein.

Applicant claims a method for treating atherosclerosis comprising administering to a subject in need thereof an effective amount of powder together with one or more activators of nuclear receptors, thereby treating the atherosclerosis.

The teachings of Levy are set forth above. Levy does not expressly teach a method of treating a disease wherein the disease is atherosclerosis. However, it would have been obvious to one ordinary skill in the art at the time the invention was made to use the method taught by Levy to provide the claimed invention because at the time the invention was made it was well known in the art of medicine that atherogenesis involves oxidative modification of low-density lipoprotein and that accelerated atherosclerosis is common in patients with diabetes mellitus, as evidenced by the teachings of Levy. For instance, Levy teaches orally administering 60 mg/day of a beta-carotene containing crude extract of *Dunaliella bardawil* to diabetic patients affected a significant reduction in LDL susceptibility to oxidation, as exhibited by increased lag time and reduction in malondialdehye (MDA) and lipid peroxides (PD). At the time the invention was made, one of ordinary skill in the art would have been motivated and one would have had a reasonable expectation of success to use the method for treating diabetes taught by Levy to provide a method for treating atherosclerosis because Levy teaches, "Increased susceptibility to oxidation of LDDL derived from patients with diabetes mellitus is associated with abnormal LDL lipid composition and antioxidant content. Natural beta-carotene dietary supplementation normalizes the enhanced LDL oxidation and consequently may be of importance in delaying accelerated development of atherosclerosis in these patients." Thus, as Levy teaches that the oral administration of

effective amounts of an extract derived from *Dunaliella bardawil* to a either a diabetic patient or a healthy patient have the beneficial functional inhibitory effect on the susceptibility of LDL to oxidative modification, one of ordinary skill in the art would have been further motivated and one would have had a reasonable expectation of success to modify the referenced method by adjusting the dose amounts of the referenced extract to provide a method for treating atherosclerosis because Levy teaches that dietary supplementation of a natural isomer mixture of beta-carotene derived from a crude extract of *Dunaliella bardawil* delays oxidation of LDL derived from patients with mellitus.

Applicant may argue that one of ordinary skill in the art would disregard the teachings of Levy because the state of the art at the time the application was filed and art subsequent thereto taught that antioxidant supplementation, such as supplementation with vitamin E or ß-carotene either singular or in combination, had no therapeutic effect on cardiovascular disease. Applicant may further argue that the state of the art showed that *in vitro* administration of antioxidants indicating beneficial therapeutic effect for the treatment of cardiovascular disease did not correlate to data *in vitro* administration of antioxidants. And, thus, Applicant may argue that the Levy prediction of ß-carotene supplementation via the administration of the referenced ß-carotene containing algal extract for the treatment of atherosclerosis is faulty at best since contemporaneous art at the time this application would have deemed Levy's showings of improved *in vitro* resistance of LDL oxidation outdated and in error. However, none of Applicant's arguments would be persuasive because while the relied

upon references appear to adequately teach away from a method of dietary antioxidant supplementation for the treatment of cardiovascular diseases, none of the references provide a commensurate teaching for dietary supplementation comprising the administration of the claim-designated ingredient for the therapeutic treatment of the claim-designated disease condition of atherosclerosis, or even diabetes mellitus. Contrary to Applicant's assertion that one of ordinary skill in the art would not look to the teachings of Levy to provide a method of atherosclerosis, given the teachings and showings of Levy neither one of ordinary skill in the art nor the skilled artisan would discount the prediction disclosed by Levy for the administration of effective amounts of the referenced crude algal extract to provide a method for the treatment of atherosclerosis in a subject in need thereof because one practicing the invention at the time the invention was made would not have looked at the cited Levy' reference in a vacuum and one practicing the invention would have looked at contemporaneous art commensurate in scope to Levy's disclosure. Firstly, Applicant should note that while Levy loosely refers to a dietary ß-carotene supplement derived from *Dunaliella bardawil*, which was used in a method to improve resistance of LDL oxidation in diabetic patients, the algal extract taught by Levy was a crude extract: "The algae were washed to remove NaCl before spray-drying; the washed powder contained ≈8% carotene." Levy further teaches, "The ß-carotene was comprised of two major isomers: all-trans (42%) and 9-cis (43%), and also α-carotene (5%) and other oxycarotenoids such as lutein, zeaxanthin and neoxanthin [citations omitted]." *See* page 55, Column 2, under "*Supplements*". Levy further teaches that blood recovered from diabetic patients

receiving the referenced algal extract contained additional carotenoids: "Our HPLC revealed the occurrence of the following carotenoids: lutein, zeaxanthin, ß-cryptoxanthin, α-carotene, all-trans carotene, 9-cis β-carotene, lycopene and lycopenic isomers", on page 56, Column, lines 14-17. Thus, while Levy loosely describes his method of treatment as showing a protective effect of β-carotene supplementation against oxidation in LDL upon a three-week dietary supplementation in diabetic patients, Levy actually exhibits the protective effect of the oral administration of effective amounts of crude *Dunliella bardawil* powder on LDL oxidation. Thus, Levy indeed teaches an *in vivo* method of treating diabetic patients at risk of developing atherosclerosis comprising the administration of effective amounts of a crude *Dunliella bardawil* powdered extract. Secondly, Applicant should note that at the time the invention was filed, Boulous taught a composition comprising each of lutein, zeaxanthin, β-cryptoxanthin, α-carotene and lyopene that was useful in the treatment of cardiovascular diseases such as atherosclerosis, which are one and the same ingredients shown by Levy to comprise the referenced crude *Dunliella bardawil* powder. Thus, at the time the invention was made, it would have been obvious to one of ordinary skill in the art and one of ordinary skill in the art would have been motivated and had a reasonable expectation of success to orally administer the crude *Dunliella bardawil* powder taught by Levy shown to have a protective effect against LDL oxidation in diabetic patients to provide the instantly claimed invention because Boulous taught that carotenoids, such as those comprising the crude extract taught by Levy, provide a protective and beneficial functional effect for the treatment of cardiovascular disease and atherosclerosis; and Levy taught that the

oral administration of effective amounts of crude *Dunliella bardawil* powder to diabetic patients at risk of developing atherosclerosis reduced LDL susceptibility to oxidation and normalized LDL levels; and the prior art taught that it was well known in the art at the invention was made that oxidized low-density lipoprotein has been implicated in the development of atherosclerosis, as readily admitted by Applicant and as taught by Levy. Hence, with regard to the administration of effective amounts of crude *Dunliella bardawil* powder together with one or more activators of nuclear receptors, thereby treating the atherosclerosis, it would have been *prima facie* obvious to one of ordinary skill in the art to combine the crude algal extract taught by Levy with the instantly claimed ingredients because at the time the invention was made it was known in the art the beneficial functional effects for the oral administration of activators of nuclear receptors in the treatment of atherosclerosis, as evidenced by the teachings of Pan, Craig and Druzgala. Firstly, Pan teaches a method of reducing the risk of or treating diabetes mellitus comprising administering an effective amount of an antihyperlipoproteinemic agent, *e.g.*, fenofibrate, gemfibrozil, clofibrate, bezafibrate, ciprofibrate and clinofibrate in combination with a cholesterol lowering drug, ACE inhibitor, in Column 9, lines 32-58. For example, in Column 15, line 58 to Column 16, line 2, Pan teaches administering gemfibrozil capsules either alone in combination with a cholesterol lowering drug, ACE inhibitor in the treatment of diabetes mellitus. Pan further teaches that the ingredients of his invention prevent the onset of coronary artery disease and atherosclerosis in mammalian species. Secondly, Craig teaches a method of treating diabetes mellitus and diabetes related disease conditions, *e.g.*, atherosclerosis, comprising the

administration of rosiglitazone. Thirdly, Druzgala teaches a method of treating disorders, such as diabetes, atherosclerosis, hypercholesterolemia, and hyperlipidemia, comprising the administration of a therapeutically effective amount of thiazaolidinedione, *i.e.,* troglitazone (for example, REZULIN), pioglitazone and rosiglitazone.

As each of the references indicate that the various proportions and amounts of the ingredients used in the claimed method of treatment are result variables, they would have been routinely optimized by one of ordinary skill in the art in practicing the invention disclosed by each of the references.

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Claims 2 and 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Itoh et al. (V and W) in view of Levy et al. (U).

Applicant's claimed invention of Claims 2, 9, 16 and 17 was set forth above. Applicant further claims the method according to Claim 2, wherein said powder is encapsulated.

The teachings of Itoh are set forth above. Itoh teaches the claim-designated methods except for wherein the powder is encapsulated. However, it would have been obvious to one of ordinary skill in the art to modify the method of disease treatment taught by Itoh by administering the reference powdered extract of *Dunaliella bardawil* in an encapsulated form to provide the claimed invention because at the time the invention

was made it was known in the art of pharmacy that the oral administration of the claim-designated algal composition in an encapsulated form was conventional, as evidenced by the teachings of Levy set forth above. At the time the invention was made, one of ordinary skill in the would have been motivated and one would have a reasonable expectation of success to modify the method of treatment taught by Itoh by administering the referenced crude powdered extract of *Dunaliella bardawil* in an encapsulated form to provide the claimed invention because Levy teaches that the oral administration of *Dunaliella bardawil* provides a mean of delivering the therapeutic algal composition. Thus, the claimed invention would have been merely a matter of judicial selection to one practicing the invention to pick and choose the form for the oral administration of the referenced algal compositions to effect a result variable for the treatment of the claim-designated disease conditions, since at the time the invention was made Itoh teaches that the oral administration of effective amounts of a crude powdered extract of *Dunaliella* had therapeutic effects for the claim-designated disease condition, and given that Levy teaches that the encapsulation of a powdered extract of the claim-designated algal extract has therapeutic beneficial effects.

According, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Claims 2 and 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Itoh et al. (V and W) and Levy et al. (U) in view of in view of Beck (A*), Chenevier

et al. (P), Clark et al. (F*) and Heyman et al. (C*). Newly applied as necessitated by amendment.

Applicant's claimed invention of Claims 2 and 16-18 was set forth above. Applicant further claims a method according to claim 2, wherein said crude *Dunaliella* powder is administered together with one or more activators of nuclear receptors. Applicant further claims the method of claim 11, wherein the activators of nuclear receptors are peroxisome proliferator-activated receptor α or γ (PPARα or PPARγ) agonists. Applicant further claims the method according to claim 12, wherein the PPARα or PPARγ agonists are selected from fibrates and thiazolidinediones. Applicant further claims the method according to Claim 13, wherein the fibrates are selected from clofibrate, fenofibrate, bezafibrate, ciprofibrate, beclofibrate and gemfibrozil. Applicant further claims the method according to Claim 13, wherein the thiazolidinediones are selected from troglitazone, BRL 49653, pioglitazone, ciglitazone, WAY-120,744, englitazone, AD 5075, darglitazone and rosiglitazone.

The combined teachings of Itoh and Levy were set forth above. The combined teachings of Itoh and Levy teach the claimed invention except for the instantly claimed ingredients. However, it would have been obvious to one of ordinary skill in the art to add the instantly claimed ingredients to the methods for reducing triglycerides and/or increasing HDL cholesterol levels in the plasma of subject taught by the combined teachings of Itoh and Levy to provide the claimed method of treatment because at the time the invention was made fibrates and thiazolidinediones were known in the art for their beneficial effect for treating the claim-designated disease conditions. Firstly, in

Column 1, lines 11-16, Beck teaches that the administration of bezafibrate is widely used for the treatment of hyperlipidaemias (hypertriglyceride-ciaias and hypercholesterolaemias); Chenevier teaches a method of treating hyperlipemia, including hypercholesterolemia and hypertriglyceridemia, comprising the administration of an effective amount of fenofibrate; and Clark suggests that the administration of clofibrate, gemfibrozil, fenofibrate and bezafibrate reduce serum cholesterol. Secondly, Heyman teaches a method of treating hypertriglyceridemia comprising administering an effective amount of a thiazolidinedione, *e.g.,* troglitazone, BRL 49653 , pioglitazone, ciglitazone, WAY-120,744, englitazone, AD 5075, and darglitazone, in combination with an RXR agonist to a subject. At the time the invention was made, one of ordinary skill in the art would have been motivated and one would have had a reasonable expectation of success to add the instantly claimed ingredients to the methods for reducing triglycerides and/or increasing HDL cholesterol levels in the plasma of subject taught by the combined teachings of Itoh and Levy to provide the claimed method of treatment because Chenevier, Beck and Clark teach that the claim-designated fibrates are effective in lowering serum cholesterol; and, in Column, 2, lines 5-11, Heyman teaches that the combination of an RXR agonist and a PPARγ agonist, *i.e.,* a thiazolidinedione, achieves synergistic action of the RXR/ PPARγ heterodimers so as to enhance adipogenic and antidiabetic effects of PPARγ.

Moreover, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit since each is well known in the art for their claimed purpose and for the following

reasons. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman,* 1943 C.D. 518. Applicants invention is predicated on an unexpected result, which typically involves synergism, an unpredictable phenomenon, highly dependent upon specific proportions and/or amounts of particular ingredients. Any mixture of the components embraced by the claims, which does not exhibit an unexpected result (e.g., synergism) is therefore *ipso facto* unpatentable.

Accordingly, the instant claims, in the range of proportions where no unexpected results are observed, would have been obvious to one of ordinary skill having the above-cited references before him.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

No claims are allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is 571-272-0964. The examiner can normally be reached on 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MICHELE FLOOD
PRIMARY EXAMINER

Michele C. Flood

MCF
July 25, 2005